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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,546	03/26/2001	Deborah J. Good	P 0279282	9489

909 7590 09/27/2002

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EXAMINER

CHEN, SHIN LIN

ART UNIT PAPER NUMBER

1632

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/816,546	GOOD ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-9 and 22-30, drawn to a transgenic ungulate having homozygous knockout prion gene, wherein said transgenic ungulate is unsusceptible to prion-related diseases, classified in class 800, subclass 14.
  - II. Claims 10-21, drawn to an isolated DNA molecule comprising at least part of an ungulate prion gene promoter linked to a selectable marker gene or reporter gene, a DNA targeting molecule capable of deleting or disrupting expression of an ungulate prion gene, and a plasmid comprising said DNA molecule, classified in class 435, subclass 320.1.
  - III. Claims 31-38, drawn to a method of making a transgenic ungulate by nuclear transfer and breeding for homozygous transgenic ungulate, classified in class 800, subclass 22.
  - IV. Claims 39-41, drawn to A transgenic ungulate having a heterologous **mutant** prion gene allele which confers an **increased** tendency to develop a prion-related spongeform encephalopathy, classified in class 800, subclass 14.
  - V. Claim 42, drawn to a method of using a transgenic ungulate to screen for or evaluate agents that is useful for treating or preventing spongeform encephalopathies, classified in class 800, subclass 3.

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- VI. Claims 43-45 and 48, drawn to a method of xenotransplantation using fetal tissue or cells of a transgenic ungulate, classified in class 600, subclass 338.
  - VII. Claims 46 and 47, drawn to a transgenic ungulate with double gene knockout including prion gene and a gene that interferes with xenotransplantation, classified in class 800, subclass 14.
  - VIII. Claim 49, drawn to a method of using transgenic bovines for producing recombinant protein, classified in class 800, subclass 4.
2. The inventions are distinct, each from the other because of the following reasons:
- Groups I, IV and VII are distinct from each other because they are drawn to transgenic ungulate that differ morphologically, physiologically and physically. A transgenic ungulate having deleted prion gene is different from a transgenic ungulate having mutant prion gene that leads to increased tendency to develop a prion-related spongeform encephalopathy because they lead to two opposite phenotypes: unsusceptible to prion-related diseases vs increased tendency develop a prion-related spongeform encephalopathy. Further, a transgenic ungulate with double gene knockout including prion gene and a gene that interferes with xenotransplantation has various gene knockout in addition to prion-gene, and it differs from those two types of transgenic ungulates set forth above phenotypically, physiologically and physically. They are different products and the search would not be coextensive. Thus, they are patentably distinct from each other and require separate search.

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Group II is distinct from groups I, IV and VII. They are drawn to different compositions having different chemical structures, physical properties and biological functions: DNA molecules vs transgenic ungulates. The search for DNA molecules does not require search for transgenic ungulates and vice versa. They have different classifications and the search would not be coextensive. Thus, group II is patentably distinct from groups I, IV and VII.

Groups III, V, VI and VIII are distinct from each other because they are drawn to materially different methods of using different transgenic ungulates as discussed above regarding groups I, IV and VII. A method of making a transgenic ungulate is different from a method of using transgenic ungulate. They are methods which differ at least in objectives, method steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They have different classifications and require separate search. Thus, they are patentably distinct from each other.

Groups I, II, IV and VII are distinct from groups III, V, VI and VIII. Groups I, II, IV and VII and groups III, V, VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.E.P.. § 806.05(h)). In the instant case the DNA molecule or DNA targeting molecule can be used to as probe for screening or used to transfect cells *in vitro* for studying biological function of prion

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gene. The transgenic ungulate can be used for disease model to study the biological function of prion gene product *in vivo* and pathology of prion-related diseases.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Scott Priebe can be reached on (703) 308-7310. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Patsy Zimmerman, whose telephone number is (703) 305-2758.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'Shin-Lin Chen' in a cursive style.